

European Registry of Clinical, Environmental and Genetic Determinants in Eosinophilic Esophagitis (EoE Connect)

Rules of participation (v.2 - 01/07/16)

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Collaborating researchers:

| Researcher | National Society | Country |
|--------------------------|--|-----------------|
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| Stephen Attwood | <i>British Society of Gastroenterology (BSG)</i> | United Kingdom |
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Introduction

The project aims to promote clinical and epidemiological studies from a large number of patients with EoE and provide a common working tool for researchers in EoE.

The database (EoE Connect) has been designed by an expert panel of international EoE experts, developed by consensus and technical work, presented and discussed at several meetings of the UEG Link Award Group and sponsored by UEG funds.

The database has different sections (see ***EoE Connect Researchers Manual***), that besides contributing to the Ha-EoE-EU project, can be used locally, such as patient registration. It is foreseen that the database could evolve in order to work with selected variables on different aspects of the disease (epidemiological, clinical, drug safety, biobanking of samples, etc.) for further exploitation, common scientific and translational purposes.

The EoE Connect registry will allow the exploitation of information for conducting clinical studies. Therefore the EoE Connect registry within the Ha-EoE-EU project has been approved by a central Clinical Research Ethics Committee (see ***EoE Connect REC approval***), and local REC approvals are encouraged as required by best practice standards and applicable ethics and legal requirements within participants.

Also the files stored in a central and secure server by a specific contractor has been registered by the *Spanish Data Protection Agency* and meet all the European legal requirements for this type of Registries, under the responsibility of the project coordinator, the SEPD, during the duration of the project and until further transfer to another interested party that eventually might take the lead after the LinkAward project.

To participate in the EoE Connect registry and benefit both from the scientific production thereof and from their usefulness locally in the management of EoE patients, the clinicians-researchers interested must get approval from their own institutions' local ethics committee and sign the ***EoE Connect Participant's Agreement*** document. The coordinating organisation will send the participant codes needed to access the website database and the ***EoE Connect Researchers Manual***.

The key element of a database might be complemented in the future with a biobank of biological samples from EoE patients in future project developments.

How to participate in the EoE Connect Registry?

To use the EoE Connect registry in a center by one or more clinician-researchers working with EoE patients, it is necessary to have signed the ***EoE Connect Participant's Agreement*** document both by the clinician-researchers and the manager (or legal person responsible) of each center/hospital.

The data included in the registry, through a website server located in Spain, is stored under the provisions of the European and Spanish Data Protection Law controller (manager or legal person). This server has been specifically dedicated and is managed by a professional company hired by the Ha-EoE-EU coordinating Society (SEPD) during the development of the LinkAward project and until further transfer to another interested party that eventually might take the lead after the LinkAward project.

To participate in the EoE Connect registry and benefit both from the scientific production thereof and from their usefulness locally in the management of EoE patients, the clinicians-researchers interested must get approval from the local ethics committee and sign the ***EoE Connect Participant's Agreement*** document. The coordinating organisation will send the participant codes needed to access the website database and the ***EoE Connect Researchers Manual***.

Also the central **Research Ethics Committee approval** as well as the project **model of informed consent** for the patients will be provided.

Proposing and presenting studies

Every center that includes EoE cases in the EoE Connect database acts as owner of the information they generated and can use it freely to develop research and scientific communications. In order to use the multicentre information collected from all participant centers included in the EoE Connect registry, a researcher/research team may request the exploitation of the information collected in the database, by proposing an specific research study. As a requirement to propose a specific study, researcher should have actively contributed to generate the information registered in EoE Connect, and submit a specific form to the Secretariat of the EoE Connect Scientific Committee.

They will be some prerequisites for the application to access the data in the central database:

1. - Having at least 30 cases included in the database.
2. – The requested study proposal must be approved by the Ethics Committee of the Hospital to which the researcher belongs. The approval report must be attached to the request.
3. - The main objective of the study should contribute to the improvement of the knowledge of an unexplored or under-explored field related to EoE. The relevance of the proposal should be supported with literature and be clarified before listing the

main objective.

4.- If a high similarity between two independent research proposals is found, they will be assessed in a first come, first serve basis. In exceptional cases, a meeting of the two research teams could be proposed.

5.- The results of the projects approved and developed in the previous year will be presented at the UEG Annual Conferences and the maximum scientific dissemination will be given to them.

European EoE Connect - Scientific Committee

The **EoE Connect Scientific Committee (EoE-C-SC)** will be composed among the members who had contributed to the creation and the implementation of the EoE Connect registry, and/or the recruitment of a significant number of patients. The organization of the Committee will be set out under the complete transparency of the project, its objectives and the establishment of its operation rules.

Currently the EoE Connect Scientific Committee members for 2016 are:

| Researcher | National Society | Country |
|-------------------------------|--|-----------------|
| Alfredo J Lucendo (Chair) | <i>SEPD (Spanish Society of Digestive Diseases)</i> | Spain |
| Ulrike von Arnim (Vice-chair) | <i>Deutsche Gesellschaft für Gastroenterologie, Verdauungs- und Stoffwechselkrankheiten (DGVS)</i> | Germany |
| Stephen Attwood | <i>British Society of Gastroenterology (BSG)</i> | United Kingdom |
| Arjan Bredenoord | <i>Nederlandse Vereniging voor Gastro-Enterologie (NVGE)</i> | The Netherlands |
| <i>Javier Júdez</i> | <i>SEPD (Technical Coordinator)</i> | <i>Spain</i> |
| Javier Molina-Infante | Asociación Española de Gastroenterología (AEG) | Spain |
| Alain Schoepfer | <i>Schweizerische Gesellschaft für Gastroenterologie (SGG) y European Society of Eosinophilic Esophagitis (EUREOS)</i> | Switzerland |
| Alex Straumann | <i>Schweizerische Gesellschaft für Gastroenterologie (SGG)</i> | Switzerland |

The **Steering Committee** of the **Ha-EoE-EU LinkAward project** will sanction the rules and standards of work, decisions and renewal of this EoE Connect Scientific Committee.

The EoE-C-SC will be renewed for the period post-LinkAward in January 2017.

The main function of EoE-C-SC is to evaluate the projects submitted for exploitation of clinical/epidemiological/genetic data, and approve its implementation if the evaluation is positive.

The EoE-C-SC is responsible for ensuring the proper functioning of the EoE Connect registry, including inter alia the management of data and policy authorship of the works that are generated from it.

The EoE-C-SC members will have granted access to all data (anonymized) of the central database. This privilege is lost when a member leaves the Committee. No other researcher will have access to the central database.

EoE-C-SC members cannot evaluate projects that come from their own center whether or not they lead, as principal investigator, the submitted proposal.

The EoE-C-SC meets in person at the annual meeting of the UEG or EUREOS. In between face-to-face annual meetings, meetings will be held via a teleconference system for decision-making.

Policy of authorship for projects supported on the EoE Connect registry

Relevant contributions of any institution participating in the project must be rewarded in the scientific production resulting therefrom. To this end, the politics of authorship of the Ha-EoE-EU projects will aim to benefit the maximum number of researchers.

In order to fulfill this philosophy, the principal investigators (PIs) of each project awarded will be responsible for proposing the list of authors for approval by the EoE Connect Scientific Committee. In the list of authors the PI will try to give maximum representation, including the maximum number of authors, who have made a significant contribution to the project and allow the publication of a paper. The order of authorship will be established considering the relative contribution of each of the researchers to the project both in terms of the number of cases brought or registered contribution to the study design, analysis of results and drafting of the manuscript. A comprehensive list will be included with as an addendum with all project contributors (collaborators). In those journals or conferences where a limited number of authors is required an insertion like “representing the EoE Connect registry” should be added after the last signatory.

The PI of each EoE Connect project is required to:

- 1.- Notify the EoE-C-SC about each scientific congresses and meetings that the study results are presented.
- 2.- Submit to the EoE-C-SC the manuscript/s of the study with proposed authors before submission for publication.

- 3.- Submit to the EoE-C-SC an explanatory document on the relative contribution of each author.
- 4.- Contact each of the participant centers from a given specific project to notify which author or clinician-researchers should represent the center.
- 5.- Present the final results of the study at the UEG Annual Conference.

Failure to comply with these regulations by the PI of a project may make it impossible to apply for new projects for a given period if the EoE-C-SC so will consider.